

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, STATE OF ILLINOIS, STATE
OF MARYLAND, STATE OF WASHINGTON,

Plaintiffs,

- against -

UNITED STATES DEPARTMENT OF HEALTH AND
HUMAN SERVICES,

Defendant.

07-CV-8621 (PAC) (RLE)

ECF Case

PLAINTIFFS' REPLY MEMORANDUM OF LAW

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PRELIMINARY STATEMENT

Plaintiff States submit this Reply Memorandum of Law in further support of their Motion for Summary Judgment. Defendant's opposition fails to overcome undisputed facts compelling the conclusion that Defendant's August 17, 2007 letter to state health officials ("the August 17 Letter") established legislative rules that were impermissibly promulgated without the notice-and-comment procedures of the Administrative Procedure Act ("the APA").

Defendant wrongly argues that it can impose broad new requirements in the State Children's Health Insurance Program ("SCHIP") by individual adjudication rather than by APA procedures. Although the uncertainties of individual cases may allow policy determinations on a case-by-case basis, the SCHIP statute does not create such uncertainties, and the new mandates effected in the August 17 Letter are not exempt from the APA.

Defendant's argument that the August 17 Letter is not legally binding because the Defendant may exercise discretion to allow exceptions to its requirements disregards the salient point that both the language of the August 17 Letter and Defendant's subsequent conduct demonstrate that Defendant expects that the Plaintiff States are bound by those requirements.

Even Defendant's post-litigation letters prove that Defendant intended these mandates to be binding on the States. While Defendant asserts that these letters support its Motion To Dismiss, they in fact demonstrate that the August 17 Letter consummated Defendant's decision-making, that this case is ripe for adjudication, and that withholding a judicial determination would injure the Plaintiff States. This Court should grant summary judgment to the Plaintiff States.

ARGUMENT

I. THE AUGUST 17 LETTER IS A BINDING RULE, ISSUED IN VIOLATION OF APPLICABLE LAW.

A. Defendant Disputes No Material Facts.

Defendant declines to dispute any of the facts in Plaintiffs' 56.1 Statement or even to respond to them in correspondingly numbered paragraphs as required in Local Civil Rule 56.1(b). Instead, Defendant generally objects to the entire document on the ground that all of the facts, except for some that it argues are really statements of law, are immaterial. Defendant's Response to Plaintiffs' Statement of Undisputed Material Facts Pursuant to Local Rule 56.1, at 1.

"Each numbered paragraph [in Plaintiffs' 56.1 Statement] will be deemed to be admitted for the purposes of the motion unless specifically controverted by a correspondingly numbered paragraph in the statement required to be served by the opposing party." Local Civil Rule 56.1(c). By arguing that the facts in Plaintiffs' 56.1 Statement are immaterial, Defendant agrees that no material facts are in dispute and that disposition by summary judgment is appropriate. *See Bldg. Service 32B-J Pension Fund v. Vanderveer Estates Hldg., LLC*, 121 F. Supp.2d 750, 754 (S.D.N.Y. 2000); *Knoeffler v. Town of Mamakating*, 87 F. Supp.2d 322, 326 (S.D.N.Y. 2000).

B. The August 17 Letter Is a Binding Legislative Rule.

The APA defines the term "rule" as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). A legislative rule "create[s] new law, rights or duties, in what amounts to a legislative act." *Sweet v. Sheahan*, 235 F.3d 80, 91 (2d Cir. 2000). Legislative rules "impose obligations on members of the public distinct from, and in addition to, those imposed by statute." *Id.*

None of Defendant's arguments permit the conclusion that it was entitled to disregard the

APA's rule-making requirements. The plain language of the August 17 Letter and Defendant's subsequent official actions to enforce it demonstrate that the letter is a binding, legislative rule subject to the notice-and-comment requirements of the APA.

1. Defendant Cannot Impose Legislative Rules Through Adjudication.

Defendant argues that it "can impose binding obligations in one of two ways: either through rulemaking or adjudication." Def. Reply Mem., at 30. But the cases on which Defendant relies for this proposition¹ all deal with interpretive rules, not legislative rules. Policy determinations must be left to adjudication when the statutory scheme creates "problems . . . which the administrative agency could not reasonably foresee" or are "so specialized and varying in nature as to be impossible of capture within the boundaries of a general rule." *Thompson*, 475 F.3d at 210 (citing *Chenery*, 332 U.S. at 202-03). SCHIP is not such a program.

Even in the case of New York, which is engaged in an adjudicative process regarding the rejection of its state plan, Defendant did not announce its new rules in an adjudication that explained why some aspect of New York's plan failed to comport with its view of the legal requirements. Rather, it announced new rules in the August 17 Letter, then mechanically applied these new rules to New York, and is now mechanically applying them to other states, including Washington. *See* Supplemental Declaration of Roger Gantz ("Gantz Suppl. Decl."), Ex. A, Enclosure. This is the quintessential path of a legislative rule, and it shows that Defendant views the provisions of the August 17 Letter as binding requirements.

¹*See W. Va. v. Thompson*, 475 F.3d 204 (4th Cir. 2007); *Alaska Dep't of Health and Soc. Services v. Ctrs. for Medicare and Medicaid Services*, 424 F.3d 931 (9th Cir. 2005); *Mobil Exploration and Producing N. Amer., Inc. v. F.E.R.C.*, 881 F.2d 193 (5th Cir. 1989); *N.L.R.B. v. Bell Aerospace Co. Div. of Textron, Inc.*, 416 U.S. 267 (1974); *S.E.C. v. Chenery*, 332 U.S. 194 (1947).

Defendant's actions also contravene 45 CFR § 92.11(b), which provides that a state plan "need meet only Federal administrative or programmatic requirements for a plan that are in statutes or codified regulations." Defendant may not simply disregard this standard, which restricts its ability to impose new requirements through adjudicative rule-making. Defendant may demand that the states follow new, binding requirements only by imposing them in codified regulations.

Defendant cannot escape the mandate of 45 CFR § 92.11(b) by labeling its rules mere policy guidance. Unlike the situation in *Pac. Gas & Elec. v. F.P.C.*, 506 F.2d 33 (D.C. Cir. 1974), Defendant has given the rules of the August 17 Letter binding force, commanded compliance with these rules under threat of sanctions, and applied the requirements in disapproving New York's plan amendment. Plaintiffs have already demonstrated that the facts here synchronize with cases in which the courts have found rules to be legislative and conflict with cases cited by Defendant where courts have found rules to be interpretive. *See* Plaintiffs' Memorandum of Law in Support of its Motion for Summary Judgment and in Opposition to Defendant's Motion To Dismiss ("Pl. Opening Mem."), at 40-46. Defendant fails to refute this and argues that this Court should reject all of these cases "as unpersuasive." Reply Memorandum of Law in Further Support of Defendant's Motion To Dismiss and Opposition to Plaintiffs' Motion for Summary Judgment ("Def. Reply Mem."), at 33. This Court should reject Defendant's urging to disregard legal precedent.

Defendant's argument rests on the premise that a future adjudication would be appropriate or necessary for states whose plans have already been approved. If, as indicated, Defendant proposes to bring compliance proceedings and withdraw its approval of state plans based on the commands of the August 17 Letter, this would not be the application of existing policy to particular issues as they arise in individual adjudications, but rather the blanket application of new rules. Thus, in

asserting that it will make future adjudications contrary to its past adjudications, Defendant acknowledges that the mandates of the August 17 Letter are not mere policy guidance but are binding rules.

2. The August 17 Letter Contains All of the Hallmarks of a Legislative Rule.

Plaintiff States are not asking this Court for individual adjudications, but by arguing that it can make policy through such adjudications, Defendant continues to treat this action as if this case were like *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm.*, 324 F.3d 726 (D.C. Cir. 2003), in which the plaintiff sought a declaration concerning its own product. Other cases upon which Defendant relies, in which the plaintiffs sought declarations regarding their individual adjudications, are similarly distinguishable.²

An agency statement is a legislative rule when it “reads like a ukase,” *Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1023 (D.C. Cir. 2000), or when it binds other parties to follow its dictates. *Croplife America v. E.P.A.*, 329 F.3d 876, 881 (D.C. Cir. 2003). The August 17 Letter certainly reads like such a ukase: it requires states that want to expand SCHIP coverage to children with family incomes above 250% of the federal poverty level to (1) impose a 12-month waiting period; (2) provide assurances to Defendant that they have already enrolled at least 95% of eligible children below 200% of federal poverty level in Medicaid or SCHIP; (3) provide assurances that private insurance for such children has not decreased by more than two percentage points over the five-year period preceding the proposed plan amendment; and (4) provide assurances that cost-sharing requirements for such children under the state’s SCHIP plan are not more favorable than “competing”

²See *Top Choice Distributors, Inc. v. U.S. Postal Service*, 138 F.3d 463 (2d Cir. 1998); *Ctr. for Auto Safety v. Nat’l Highway Traffic Safety Administration*, 452 F.3d 798 (D.C. Cir. 2006); *In re Combustion Equip. Assocs., Inc.*, 838 F.2d 35 (2d Cir. 1988).

private plans by more than one percent of the family income, unless the state's plan imposes the maximum five percent family cap. Arnold Decl., Ex. 9. These explicit requirements are not included in the SCHIP statutes or codified regulations. They are brand new obligations.

Further, the August 17 Letter is couched in terms of mandatory, presently binding language. It repeatedly directs States that it "will expect" them to follow the new requirements and instructs affected states to amend their State Plans to conform to the requirements or face potential "corrective action" by August 2008. *Id.* That Defendant gave states a 12-month grace period in which to modify their plans to meet the new requirements does not negate the fact that Defendant gave states binding direction on August 17, 2007 – requirements that Defendant expects states to follow. These facts are similar to those in *Community Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987), in which the court recognized that the FDA's use of the term "will be deemed to be adulterated" in its contamination standards imposed a present, binding requirement. *Id.* at 947. They stand in marked contrast with *Cement Kiln Recycling Coalition v. E.P.A.*, 493 F.3d 207 (D.C. Cir. 2007), on which Defendant relies, in which the guidance document at issue described its provisions as "recommendations" and explicitly declared that it did "not impose legally binding requirements." *Id.* at 227. Similarly distinguishable is *Public Citizen, Inc. v. U.S. Nuclear Regulatory Commission*, 940 F.2d 679 (D.C. Cir. 1991), in which the language of the policy statement "sent mixed messages" as to whether it was a substantive rule. *Id.* at 683.

The governing statute merely requires a State Plan to describe the measures it will use to avoid crowd-out. 42 U.S.C. § 1397bb(b)(3)(C). Similarly, the SCHIP regulations simply require the state to describe "reasonable procedures" it will use to avoid crowd-out. 42 C.F.R. § 457.805. *See* Arnold Decl., Ex. 9. These general requirements afford the Plaintiff States great flexibility in

designing their SCHIP programs. Defendant argues that these new mandates are not legislative rules because they are not binding on Defendant. Def. Reply Mem., at 34. Irrespective of whether these requirements purport to bind the Defendant, they plainly bind the *Plaintiff States*, which are no longer free to compose plans with the substitution-prevention procedures that they consider appropriate or to utilize their own long-standing definitions of family income. Thus, the August 17 Letter is a legislative rule.

Defendant offers no support for its contrary assertion that the August 17 Letter “is not ‘self-operative,’ is not ‘effective immediately,’ and does not have the ‘status of law.’” Def. Reply Mem., at 10. Nor does Defendant support its assertion that the August 17 Letter merely announces things that it “hopes” to implement at some future time. Def. Reply Mem., at 34 (citing *Pacific Gas*, 506 F.2d at 38). Indeed, Defendant’s communications with the Plaintiff States show the opposite. Arnold Decl. ¶ 26 and Exs. 9, 10, 14; Gantz Decl. ¶¶ 31-34 and Ex. B; Gantz Suppl. Decl., Ex. A; Cornell Decl. ¶¶ 4-5 and Ex A; Tucker Decl. ¶¶ 16-17 and Ex. 3. Statements made by counsel in litigation have no weight when they contradict earlier agency statements. *Hoctor v. Dep’t of Agriculture*, 82 F.3d 165, 171 (7th Cir. 1996).

Apparently realizing that its counsel’s assertion in his initial Memorandum of Law that the August 17 Letter had little or no force was contrary to the evidence, Defendant has now, after receiving the Plaintiff States’ answering papers, issued new self-serving documents (the May 7, 2008 and Rhode Island Letters) endeavoring to show that the August 17 Letter did not mean what it said. These made-for-litigation documents cannot overcome the unmistakable import of the August 17 Letter itself and Defendant’s characterization of it before the litigation commenced.

Nor does Defendant’s assertion that the Plaintiff States have no legal obligation to comply

overcome Defendants' own actions where Plaintiff States have already seen a disapproved SPA (New York) or are facing the threat of a disapproved SPA (Washington) or the threat of losing millions of dollars in federal funds as the result of a compliance proceeding or non-renewal (Maryland). Compliance in the face of such a threat is not voluntary; it is the dilemma posed by the coercion of choosing between abandoning one's rights or risking prosecution, which "was the very purpose of the Declaratory Judgment Act to ameliorate." *Medimmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764, 773 (2007). Defendant's actions to enforce the letter, and its significant departure from past practices, demonstrate that the letter is a binding, and therefore legislative, rule. *See Sweet*, 235 F.3d at 91. Under governing law, it was required to be adopted through APA-rulemaking. 45 C.F.R. § 92.11(b).³

3. Defendant's Conduct Demonstrates that the August 17 Letter Is a Legislative Rule

Defendant claims that the Plaintiff States merely rely on "preliminary and informal" communications from Defendant. Def. Reply Mem., at 35. However, the August 17 Letter was a formal letter issued to all State Health Officials, a customary means by which Defendant communicates significant changes to states; Defendant rejected New York's State Plan Amendment in a formal letter dated September 7, 2007, Arnold Decl., Ex. 10; and issued a "stop the clock" letter dated April 24, 2008, to Washington under section 2106(c) of the Social Security Act. Gantz Suppl.

³ On April 17, 2008, United States Senators Rockefeller and Snowe released to the public two opinions by United States Government agencies that the August 17 Letter violated the Congressional Review Act, 5 U.S.C. §§ 801-808, one by the Government Accountability Office and the other by the Congressional Research Service. Reply Declaration of John M. Schwartz, Exs. A and B. As part of both opinions, these agencies concluded that the August 17 Letter was a binding "rule," as defined in the APA, a definition incorporated by reference in the Congressional Review Act. Copies of these opinions were provided to this Court and Defendant's counsel by letter of April 21, 2008.

Decl., Ex. 1, at 2. As discussed in Point I(B)(4) below, Defendant's subsequent approval of one state's proposed amendment to its SCHIP plan demonstrates that the contents of the August 17 Letter are rules. These communications are more than "preliminary and informal" actions of Defendant.

4. Defendant's Newfound Purported Flexibility Does Not Diminish the Fact that the August 17 Letter Imposes New, Binding Requirements.

Defendant argues that the August 17 Letter does not consummate its decision-making because, in the months since Plaintiff States filed this action, Defendant has made statements that purportedly clarify or allow exceptions to the rules announced in the August 17 Letter. Defendant's arguments are unavailing. *See* Def. Reply Mem., at 4-6.

Defendant first cites to Congressional testimony of CMS Director Dennis G. Smith that "a number of [unspecified] states are already meeting the 95 percent goal." Def. Reply Mem., at 4. Mr. Smith's testimony does not in any way prove that the standards of the August 17 Letter are not rules; indeed, the fact that Defendant considers it noteworthy that the "goal" imposed by Defendant is being met shows that Defendant is requiring adherence to the letter.

Defendant next cites to its letter dated May 7, 2008, to state health officials, issued less than two weeks before filing its reply papers. This letter also demonstrates that Defendant treats the August 17 requirements as rules to which states must adhere. In it, Defendant announces its intent to maintain its pre-litigation position, with only two exceptions: (1) it emphasizes that the 12-month period of uninsurance required in the August 17 Letter is "the standard," but Defendant would consider "alternative proposals" and "exceptions" that are supported by justifications and data; and (2) it states that the requirement in the August 17 Letter that each state assure that it has covered 95% of families under 200% of the FPL who are eligible for SCHIP or Medicaid can be supported by demonstrating private coverage as well, and it expresses an intention to allow states to rely on various

data sources to make such assurances. Def. Reply Mem., at 5; Turner Second Decl., Ex. A, at 2. The narrow and limited “exceptions” that Defendant may allow to the August 17 requirements do not detract from the basic fact that these requirements are rules. Even if Defendant may be flexible in individual cases about the data source, the 95% enrollment standard remains a requirement that a state must establish.

Defendant also submits its letter to the Director of Rhode Island’s Department of Human Services dated May 9, 2008 (Turner Second Decl., Ex. B, “the Rhode Island Letter”), in which Defendant approves Rhode Island’s SCHIP plan. However, this approval demonstrates only that Defendant may grant exceptions to its announced requirements in its discretion. For example, it permits Rhode Island to structure its own statistics instead of using the nationally uniform United States Census Bureau Current Population Survey, and it approves the complete elimination of the 12-month waiting period required in the August 17 Letter by the use of a premium assistance program. Turner Second Decl., Ex. B.

First, the fact that a law may be altered in the future does not insulate it from judicial review. *U.S. Gypsum Co. v. Muszynski*, 161 F. Supp.2d 289, 291-92 (S.D.N.Y. 2001) (change in criteria for issuing permits was reviewable because the defendants’ actions, including retraction of prior determinations, the denial of the plaintiff’s permit, the demand for compliance and the refusal to change their position, demonstrated that the new standard was “binding and resulted in tangible legal consequences for plaintiff”); *Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1022 (D.C. Cir. 2000). Indeed, the fact that an agency deems it necessary that a regulated entity obtain an exception in order to deviate from its standards demonstrates that the standards are binding. *See Community Nutrition*, 818 F.2d at 947 (“[t]his view of [the FDA’s] action levels – as having a present, binding

effect – is confirmed by the fact that FDA considers it necessary for food producers to secure *exceptions* to the action levels”); *Gen. Elec. Co. v. E.P.A.*, 290 F.3d 377, 384 (D.C. Cir. 2002) (allowing for exceptions “does not undermine the binding force of the Guidance Document”). Thus, Defendant’s post-litigation decision to give Rhode Island an apparent exemption from these rules only further demonstrates their binding nature.

Defendant gets no help from *Ohio Forestry Ass’n v. Sierra Club*, 523 U.S. 726 (1998). There, the challenged plan imposed no rules, and plaintiff Sierra Club could not “point . . . to any . . . way in which the Plan could now force it to modify its behavior in order to avoid future adverse consequences.” *Id.* at 734. Here, by contrast, the August 17 Letter forces all Plaintiff States to follow the dictates of the Letter in order to avoid the consequences of disapproval of a plan amendment (New York) or a compliance proceeding at which their current plans will be retroactively disapproved (Washington and Maryland).

Second, Defendant’s own statements continue to demonstrate that the August 17 Letter imposed new mandates on the Plaintiff States. Defendant reiterated, “The 12-month period of uninsurance is the standard by which States will be evaluated.” Second Turner Decl., Ex. A. Defendant similarly reiterated that it will require “[t]he assurance that at least 95 percent of children in the State with family incomes below 200 percent of the FPL have coverage.” *Id.* Calling this mandate an “achievable goal” and suggesting certain sources of data to use to fulfill such mandates does not diminish their mandatory nature.

Third, Defendant offers no basis for its conclusion that Rhode Island’s premium assistance program will prevent crowd-out. Apparently Defendant has chosen to renew Rhode Island’s waiver, pursuant to 42 U.S.C. § 1315(a), without this particular condition, for no reason other than its own

whim. Defendant has not extended the same largesse to Maryland, whose SCHIP program is also a Medicaid-expansion waiver program, even though Maryland also employs several crowd-out-prevention measures. Tucker Decl. ¶¶ 6, 11-14.

Defendant appears to be arguing that it can impose these rules on the States by letter but can arbitrarily and capriciously enforce them or not as it sees fit. Before the August 17 Letter, Plaintiff States relied on 45 C.F.R. § 92.11(b), which requires Defendant to approve all state plans that comport with statutes and codified regulations. Defendant's alteration of this standard without adherence to APA directives, followed by its erratic application of the new requirements when confronted by advice as to the workability of the new mandates, highlights one of the principal purposes of the APA, to ensure "fairness and informed decisionmaking" by "affording interested persons notice and an opportunity to comment." *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1979).

C. Defendant May Not Impose New Requirements Under the Guise of Modifying Its Interpretation of Existing Statutes and Regulations.

Defendant argues that it may impose the rules of the August 17 Letter based solely on "the states' existing obligation to provide coverage to uninsured, low-income children in an 'effective and efficient manner'" and to include "reasonable procedures" to prevent crowd-out. Def. Reply Mem., at 37. According to Defendant, the August 17 Letter merely modifies its interpretation of what is a "reasonable" crowd-out procedure under 42 C.F.R. § 457.805, which Defendant may alter as circumstances evolve, at any time, without the necessity of rule-making. Def. Reply Mem., at 37-41. Defendant asserts that what may have been "deemed reasonable in the past[]" can no longer be considered reasonable now, and that more vigorous efforts to combat crowd-out [require] specific higher benchmarks that the agency intends to use." Def. Reply Mem., at 41. Defendant misinterprets its authority under the APA's provisions for interpretive rules.

As noted above, an agency may not impose new requirements through an interpretive rule, but may only “declare . . . its understanding of what a statute requires.” *American Min. Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1110 (D.C. Cir. 1986) (internal quotation omitted). An interpretive rule is “based on specific statutory provisions,” whereas a legislative rule “is instead ‘based on an agency’s power to exercise its judgment as to how best to implement a general statutory mandate.’” *Id.* An interpretive rule “explains an existing requirement; it does not impose an ‘additional’ one.” *United States v. Picciotto*, 875 F.2d 345, 348 (D.C. Cir. 1989). Where a statute or rule “is itself very general, using terms like ‘equitable’ or ‘fair,’ and the ‘interpretation’ really provides all the guidance, then the latter will more likely be a substantive regulation.” *Paralyzed Veterans of Amer. v. D.C. Arena LP*, 117 F.3d 579, 588 (D.C. Cir. 1997), *cert. denied*, 523 U.S. 1003 (1998) (citing *Picciotto*, 875 F.2d at 348). An agency may not “promulgate mush and then give it concrete form only through subsequent less formal ‘interpretations.’” *Paralyzed Veterans*, 117 F.3d at 584.

In the instant case the statutes and regulations on which Defendant relies provide significant flexibility to the states: Plaintiff States must provide coverage “in an effective and efficient manner” and include “reasonable procedures” to prevent crowd-out. 42 U.S.C. §§ 1397aa(a), 1397bb(b)(3)(C) & (E); 42 C.F.R. § 457.805. Neither the statute nor the regulation prescribes any “description” or “procedures” or definition of substitution. The August 17 Letter imposes additional, more specific requirements. This confirms that the letter establishes legislative rules. While Defendant correctly asserts that it has general authority to evaluate whether the procedures described in a state plan comply with program objectives, Def. Reply Mem., at 38, it does not follow that Defendant may dictate the precise, specific, and detailed mechanisms that states must employ without utilizing the

normal rulemaking process.⁴

The instant case greatly resembles *American Frozen Food Inst. v. U.S.*, 855 F. Supp. 388 (Ct. Int'l Trade 1994), where the governing statute required food importers to mark packaging conspicuously with the country of origin. *Id.* at 391 n.2. When the Customs Department imposed specific type size and style requirements for packaging, the court found that such requirements imposed new requirements amounting to legislative rules because the “narrow range of sizes and styles” did not “interpret the meaning of ‘conspicuous,’ or any other term in the statute, but rather impose additional requirements for marking.” *Id.* at 396 (emphasis added). Just as the governing statute in *American Frozen Foods* afforded a broad array of methods that could have “conspicuously” marked food packages, a broad array of “reasonable procedures” can similarly ensure against crowd-out. The statutes and existing regulations do not dictate the employment of any single set of procedures, and Defendant previously admitted that its existing rule affords *states* flexibility to choose the methods best suitable for their individual circumstances: “[the crowd-out rule] permits State flexibility and implementation of policies based on the emerging research regarding substitution and on State experiences with substitution.” 66 Fed. Reg. 2602 (Jan. 11, 2001). Defendant’s present attempt to eliminate the flexibility afforded states through existing statutes and rules and impose upon them a set of specific, detailed crowd-out procedures cannot fairly be characterized as “interpretive.”

Because the purported reinterpretation of the August 17 Letter significantly enlarges existing rules, such a reinterpretation still requires the notice-and-comment procedure that would be required to change the underlying regulation. *Environmental Integrity Project v. E.P.A.*, 425 F.3d 992, 995

⁴Defendant cannot even apply the regulations requiring reasonable crowd-out prevention measures to Maryland, which operates not an SCHIP program subject to the normal SCHIP statute and regulations, but rather a Medicaid expansion with a waiver according to § 1115 of the Social Security Act. 42 U.S.C. § 1315(a).

(D.C. Cir. 2005). Otherwise, “an agency could easily evade notice and comment requirements by amending a rule under the guise of interpreting it.” *Id.* Here, the requirements of the August 17 Letter significantly depart from Defendant’s prior practice of recognizing the flexibility afforded to states under its existing codified regulations. Defendant has consistently approved SCHIP expansions above 250% FPL without imposing the August 17 Letter requirements. While states adopted various crowd-out methods (including waiting periods of different lengths and a variety of cost sharing approaches), no State Plan expanding SCHIP coverage approved by Defendant prior to the August 17 Letter included all of the requirements of that letter. Declaration of Cynthia R. Mann ¶ 22. Because these changes are so stark, Defendant cannot evade the notice-and-comment requirements even if these changes were mere reinterpretations of existing rules and statutes.

Indeed, Defendant concedes the August 17 Letter is a change in prior policy, first at page 39 of its Reply Memorandum (“The SHO Letter ...[is] a change in policy based on accumulated nationwide-experience and data...”) and next at page 41 (“[the letter] concededly marks a change from the agency’s past *sub*-regulatory practice”).⁵ Defendant contends, however, that it can impose its new rules because Plaintiff States “can contest this policy in the adjudicative process.” Def. Reply Mem., at 39. Defendant did not allow New York to contest this policy when it disapproved of New York’s Plan Amendment #10. Arnold Decl. ¶ 21 and Ex. 10. Nor is Defendant allowing New York to contest this policy in its internal reconsideration process. Arnold Decl. ¶ 22 and Ex. 12.

This change in policy is of sufficient magnitude and consequence to require the conclusion that it is a legislative rule. The directives are thus subject to notice-and-comment procedures and should be stricken for Defendant’s failure to follow those procedures. “Attempts to avoid these

⁵Curiously, Defendant does not identify the “experience and data” which led it to impose these requirements.

procedures, even when engaged in the best of intentions, do not, in the long run, further the interests of anyone.” *Benten v. Kessler*, 799 F. Supp. 281, 291 (E.D.N.Y. 1992).

II. EVEN DEFENDANT’S NEW FACTS AND ARGUMENTS SHOW THAT THE AUGUST 17 LETTER IS A RULE AND THAT PLAINTIFFS’ CLAIM IS RIPE.

As noted in Point I above, Defendant has argued that its newly created evidence – Mr. Smith’s congressional testimony, the Letter of May 7, 2008, and the Rhode Island Letter of May 9, 2008 – shows an agency flexibility inconsistent with a final and binding legislative rule. Def. Reply Mem., at 35-36. Defendant also relies heavily on these documents in its reply in further support of its motion to dismiss. The general rule in this Court is that factual arguments raised for the first time in reply should not be considered. *See JSC Foreign Economic Ass’n Technostroyexport v. Weiss*, 2007 U.S. Dist. LEXIS 28954 at *23 (S.D.N.Y. April 18, 2007); *Hummingbird USA, Inc. v. Texas Guaranteed Student Loan Corp.*, 2007 U.S. Dist. LEXIS 4596 at *6 (S.D.N.Y. January 22, 2007); *see also Thomas v. Roach*, 165 F.3d 137, 146 (2d Cir. 1999) (rule applied to appellate reply briefs). If this Court considers these arguments, then it should also consider Plaintiffs’ response to them.

A. The August 17 Letter Consummated Defendant’s Decision-Making and Is Binding on the States.

Plaintiff has discussed the finality and the binding nature of the August 17 Letter in Point I.B, *supra*. That discussion is applicable to the issue of whether it was final and binding for purposes of the Court’s ripeness inquiry. The post-litigation documents on which Defendant offers as more recent guidance, expressing Defendant’s intent to consider “exceptions” and “alternatives,” while continuing to insist on its August 17, 2007, pronouncements as the “standard,” simply confirm that compliance with its terms are the expected norm. Indeed, shortly before issuing the May 7, 2008 Letter and the Rhode Island Letter, Defendant responded on April 24, 2008, to Washington’s

proposed State Plan Amendment submitted April 21, 2008, by categorically stating that “[b]ecause the State is proposing an income level above 250 percent of FPL, Washington will need to adhere to the August 17th 2007 State Health Official (SHO) requirements.” Gantz Suppl. Decl., Ex. A, Enclosure ¶ 4(3).

B. The Court Has an Adequate Factual Record.

Relying primarily on *Florida Power & Light Co. v. Lorion*, 470 U.S. 729 (1985), Defendant contends that the courts should not review its new rule in the absence of a complete record developed in an administrative hearing. Def. Reply Mem., at 11-12. In *Fla. Power*, however, the Supreme Court held precisely the opposite: that a citizen’s petition requesting that the agency institute a proceeding to suspend a license, which the agency had denied without a hearing, fell within the narrow judicial review jurisdiction that the applicable statute conferred on the courts of appeals, *despite* the absence of a hearing record. *Id.* at 734-35, 746. As demonstrated in Point II(C) below, the Plaintiff States’ claims in the case at bar are *outside* the scope of the statutory judicial review.⁶

Defendant also argues that the Plaintiff States’ procedural claim – that the August 17 Letter was a legislative rule that required notice and comment – “could benefit from further factual development, of a kind,” *i.e.*, that the states should await actual applications of its new policy in plan-conformity determinations. Def. Reply Mem., at 12. It relies on *Public Citizen* and *Hudson v. Federal Aviation Administration*, 192 F.3d 1031 (D.C. Cir. 1999), both of which rejected the challenges of citizen groups to agency “policy statements” that indicated a relaxation of prior safety

⁶ *New York Dep’t of Social Services v. Shalala*, 21 F.3d 485 (2d Cir. 1994), also cited by Defendant (Def. Reply Mem., at 11), is inapposite. There the court declined to consider an argument that had not been raised by the state agency in its completed administrative appeal from the Health Care Financing Administration’s partial disallowance of federal funding. It did not suggest that the state would have no judicial remedy had its claim been outside the narrow confines of an administrative appeal from a funding disallowance.

requirements. Def. Reply Mem., at 12-14. In *Public Citizen*, however, the court found that the language of the policy statement itself “sent mixed messages” as to whether it was a substantive rule (940 F.2d at 683), whereas in *Hudson*, the court found that the tentative language of the “policy statement” itself confirmed it was not a rule that required APA notice and comment procedures. 192 F.3d at 1035. Neither of these cases is applicable to the present case, in which the language of the August 17 Letter is uniformly mandatory (Point I.B.2, *supra*; Pl. Opening Mem., at 21- 24) and has had immediate, substantial and concrete impact on the Plaintiff States. Point I.B.3, *supra*; Pl. Opening Mem. at 17-21. To the extent that the cases suggest that an agency’s acts under a new policy can help determine whether it is a rule, Defendant’s dealings with Plaintiffs Washington, Maryland and New York, as well as its Congressional testimony, before Plaintiffs commenced this action, provides such conduct. Pl. Opening Mem., at 23-24, 37-38.

Defendant contends that only final decisions rendered after administrative hearings should be considered as agency conduct in determining whether the August 17 Letter is a rule. It urges that what it characterizes as “informal” communications (*e.g.*, congressional testimony, letters to state SCHIP directors or conference calls with state representatives) should be disregarded. Def. Reply Mem. at 14 - 16. As its principal authority for this position, however, it cites *National Audubon Society v. Dep’t of the Navy*, 422 F.3d 174 (4th Cir. 2005), in which the Fourth Circuit affirmed the district court’s conclusion that an environmental impact statement (EIS) was inadequate, noting that the test for adequacy of an EIS is an objective one, rather than the subjective intent of the agency. *Id.* at 198. The *finality* of agency action, however, even if not apparent on the face of the document, can be evidenced by the agency’s subsequent refusal to reconsider or its explanations that it is

conclusive. *Whitman v. American Trucking Ass'ns, Inc.*, 531 U.S. 457, 479 (2001); *Muszynski*, 161 F. Supp.2d at 291-92.⁷

Defendant argues that “whatever representations CMS staff made” prior to the litigation “have now been superseded by more recent CMS guidance,” referring to Defendant’s May 7, 2008, Letter to State Health Officials (Turner Second Decl., Ex. A) and the Rhode Island Letter (*Id.*, Ex. B). It presents these documents as “more definitive and up-to-date than any of the communications on which plaintiffs rely” and show that “CMS will hear states out on any proposed alternatives to the procedures and assurances” in the August 17 Letter. Def. Reply Mem., at 16. In effect, Defendant argues that it has altered its course. This can help Defendant only if it can show “that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur.” *Seidemann v. Bowen*, 499 F.3d 119, 128-29 (2d Cir. 2007). Defendant’s characterization of its practice as “a work in progress that is not yet reflected in any pattern of final adjudicative decisions,” together with the adjustments it has recently made in response to this litigation, makes it clear that Defendant may reverse course again. Indeed, it seems to be insisting on its right to remain unpredictable.

In any event, the May 7, 2008, Letter does little to ameliorate the harm inflicted by the August 17 Letter. As noted in Point I.B.4 above, it demonstrates Defendant’s intent to stand fast in its pre-litigation position, with only two modest exceptions. Defendant is still insisting on the 12-month uninsurance period as the standard, and its vague expression of intent to consider “exceptions” or

⁷ Defendant also cites *American Trucking Ass'ns, Inc. v. Interstate Commerce Commission*, 747 F.2d 787 (D.C. Cir. 1984), in which then-Judge Scalia noted that “concrete results” of administrative adjudications would be necessary to determine the disputed *scope and meaning* of an ambiguous ICC policy statement. *Id.* at 790. Six years later, however, now-Justice Scalia also wrote the majority opinion in *Whitman*, *supra*, in which the agency’s behavior, even without the “conventional procedural accoutrements of finality,” were enough to sustain the *finality* of its announced policy. 531 U.S. at 479.

“alternatives” simply proves the rule. The possible inclusion of private coverage to satisfy the 95% coverage requirement is of limited value because SCHIP is based on the assumption that very few of the under 200% population can obtain access to or afford private insurance.

As for the Rhode Island Letter, as discussed above, it demonstrates no more than that Defendant may from time to time grant exceptions or alternatives to its announced requirements. It does not show that Defendant will refrain from improperly enforcing the requirements of the August 17 Letter in other situations; rather, it simply demonstrates Defendant’s intent to demand compliance while its enforcement intentions remain unpredictable.

C. 42 U.S.C. § 1316(a) Does Not Deprive This Court of Subject Matter Jurisdiction Under 28 U.S.C. § 1331.

Only upon a showing of “clear and convincing evidence” of a contrary legislative intent should the courts restrict access to judicial review. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 141 (1967). Thus, the Defendant here has the heavy burden of overcoming the strong presumption that Congress intended to prohibit judicial review of the August 17, 2007 letter. *See Dunlop v. Bachowski*, 421 U.S. 560, 567 (1975); *Abbott Laboratories*, 387 U.S. at 141. Defendant’s argument that 42 U.S.C. § 1316(a) forecloses judicial review does not overcome the strong presumption that this Court has subject matter jurisdiction under 28 U.S.C. § 1331.

The Medicaid statute incorporated by reference in SCHIP [42 U.S.C. § 1316(a)(3)], provides for judicial review only in certain narrow categories of disputes: the Secretary’s determination as to whether “any State plan” submitted for approval or already in operation conforms to the statutory requirements. 42 U.S.C. §§ 304, 1204, 1316(a)(1) and (2), 1354, 1384 or 1396c. The Plaintiff States, however, are challenging a broad new policy that Defendant is applying to all states, not a disapproval of an individual state’s plan. The appropriate venue is therefore not the “special statutory

review proceeding” specified by 42 U.S.C. § 1316(a)(3), but rather the alternative form of proceeding described in the APA as “any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction . . . in a court of competent jurisdiction.” 5 U.S.C. § 703. *See also Bowen v. Massachusetts*, 487 U.S. 879, 907 n. 42 (1988) (although Congress provided other self-enforcing causes of action by creating both an express right and the remedy, it also created a right in the Medicaid Act without an express remedy, “knowing that the APA provided for review of this sort of agency action”).

The SCHIP statute borrows 42 U.S.C. § 1316 (relating to administrative and judicial review), “but only insofar as consistent with this title.” 42 U.S.C. § 1397gg(e)(2)(B). Defendant has made no effort to analyze Section 1316 in light of the “strategic objectives” of the SCHIP statute (§ 1397gg(a)(2): “increasing the extent of creditable health coverage among targeted low-income children and other low-income children”), nor has it argued that anything in the SCHIP statute as a whole supports the foreclosure of this suit. The mere fact that a statute makes some acts subject to administrative or judicial review does not support an implication of exclusion as to others. *Abbott Laboratories*, 387 U.S. at 141; *Stark v. Wickard*, 321 U.S. 288, 309 (1944). Section 1316(a) is a remedy for a state to challenge federal disapproval regarding *a state plan* by the Secretary; it does not convert all disputes between the state and the Secretary over procedure or policy into “plan-conformity issues.” Def. Reply Br., at 22. It is thus very different from the cases relied on by Defendant, *see* Def. Reply Mem. at 27, like *NRDC v. Johnson*, 461 F.3d 164, 172 (2d Cir 2006) (“*any issue*” as to which review obtainable under statute not subject to other judicial review) (emphasis added) or *NRDC v. Abraham*, 355 F.3d 179, 192 (2d Cir. 2004) (“[*a*]ny person . . . adversely affected by a rule prescribed” under statute may file in court of appeals) (emphasis added). *But cf. Furlong*

v. Shalala, 238 F.3d 227, 234 (2d Cir. 2001) (challenges to agency policy, rather than calculation of benefits, permitted in district court despite same prohibition as in *Johnson*). “[A]bsent a specific grant of statutory authority elsewhere, subject matter jurisdiction regarding review of agency rulemaking falls to the district courts under federal question jurisdiction.” *Abraham*, 355 F.3d at 192-93.

Defendant inappropriately relies on remarks by Senator Jacob Javits supporting the judicial review of administrative decisions “prior to actual implementation of a proposed change in the State’s existing plan,” which would avoid both the necessity of withholding or recouping Federal funds and “disruption in the operation of the existing approved Stated plan.” 111 Cong. Rec. 3068 (1965), quoted in *New Jersey*, 670 F.2d at 1276. Here, however, Defendant is trying to use Section 1316(a) to block review of new agency requirements while demanding drastic changes in existing plans and denying proposed amendments. Def. Reply Mem., at 7. Defendant argues that if the aggrieved state prevails in that future review, it would receive the very recoupment of withheld funds that Senator Javits wanted to avoid. *Id.* at 19.

Heckler v. Ringer, 466 U.S. 602 (1984) (Def. Reply Br. at 22-24), is even more unlike the instant case. In *Heckler*, the statute at issue expressly prohibited any review of decisions by the Secretary except as provided in the statute and provided that “[n]o action against the United States, the Secretary, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim arising under this subchapter.” 466 U.S. at 615 n.10 (quoting 42 U.S.C. § 405(h)). Congress clearly knows how to bar federal-question jurisdiction in the District Courts, but it has not done so in Section 1316(a), which supplements but does not replace traditional forms of judicial review. *Abbott Laboratories*, 387 U.S. at 142.

D. Withholding Review Would Impose Hardship on Plaintiffs.

Defendant's assertions that no state will suffer any harm from the August 17 Letter until it completely exhausts its administrative and statutory legal remedies, after either a disapproval of its plan amendment or an enforcement proceeding if Defendant chooses to commence one, Def. Reply Mem., at 17-21, defy reality. Washington, which already covers children with family incomes above 250% of FPL (with Defendant's permission), has just received a flat statement in response to a recently submitted plan amendment that to obtain approval it will "need" to comply with all the requirements of the August 17 Letter. Gantz Suppl. Decl., Ex. A. Maryland already "has received communications from CMS requesting its compliance with the SHO letter," Def. Reply Mem., at 17-18 n.5, and besides the threat of compliance proceedings, is subject to non-renewal of its plan after "periodic reviews" and consequent loss of funding because of its special status in a demonstration program pursuant to 42 U.S.C. §1315. *Id.* at 20 n. 7.

Defendant contends that an "extensive, structured negotiation process" between Defendant and the state should moderate any immediate harm to Maryland. Def. Reply Mem., at 20 n.7. On the contrary, during Maryland's current program renewal process, Defendant has demanded Maryland's full, immediate and future compliance with the August 17 Letter's terms, without engaging in any of the flexible "negotiation" Defendant suggests its Reply Memorandum that it will undertake. *See* Declaration of Cheryl Camillo ¶¶ 4-10 and Ex. 1, at 5. Similarly, although Defendant argues that New York can pursue an administrative appeal of its SPA denial, Defendant has redefined the issues in that appeal to exclude from consideration any challenge to the validity of the new rules the August 17 letter imposed. Def. Reply Mem., at 18-19; Arnold Decl., Ex. 12. Defendant's suggestion that these states can defer until August 2008 the logistical, regulatory and even legislative

modifications that would be necessary to bring their plans into compliance with Defendant's new demands, if such compliance is possible, is frivolous. The states cannot risk a non-compliance proceeding or the loss of federal funding for a significant part of their programs by ignoring the requirements.

To support its position, Defendant principally relies upon *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726 (D.C. Cir. 2003). *Reliable Automatic* is inapposite because, unlike the present case, it was not a direct challenge to the validity of the governing rule's adoption. The better precedent is the plaintiff's challenge to an EPA directive in a press release in *CropLife America v. E.P.A.*, 329 F.3d 876 (D.C. Cir. 2003). Distinguishing *Reliable Automatic* and rejecting the EPA's argument that the claim was unripe because it could proceed via administrative appeal, the court held, "The disputed directive concretely injures petitioners" because "[t]here is no doubt that the injury is caused by the new rule, nor is there any doubt that this injury can be redressed if the court vacates the new rule and reinstates the agency's previous practice." *Id.* at 884. *See also Ciba-Geigy Corp. v. E.P.A.*, 801 F.2d 430, 433 (D.C. Cir. 1986) (vacating a ripeness dismissal where the agency correspondence warned that in the near future any non-compliant product shipments "will be considered misbranded," and "subject to appropriate enforcement action" because such language "admit[ted] of no ambiguity," was "definitive," and contained "the expectation that regulated parties will conform to and rely on this interpretation."

The presence of immediate and substantial hardship to Plaintiffs renders this matter ripe for judicial review, and this court should resolve any doubts as to ripeness in Plaintiffs' favor. "Courts confronted with close questions of ripeness are appropriately guided by the presumption of

reviewability, especially when the affected person is confronted with the dilemma of choosing between disadvantageous compliance or risking imposition of serious penalties.” *Id.* at 434.

CONCLUSION

The language of the August 17 Letter and all of Defendant’s subsequent conduct, including issuing the letters that Defendant relies on here, prove that the August 17 Letter promulgated legislative rules. Plaintiff States respectfully request that this Court grant partial summary judgment on that issue and rule that the mandates of the August 17 Letter were subject to the notice-and-comment procedures of the Administrative Procedure Act.

Dated: New York, New York
June 6, 2008

Respectfully submitted,

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